

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,

Plaintiffs,

v.

NOVADOZ PHARMACEUTICALS LLC,
MSN PHARMACEUTICALS INC., MSN
LABORATORIES PRIVATE LIMITED,

Defendants.

No. 25-CV-00849-EP-JRA

DEFENDANTS' ANSWER AND AFFIRMATIVE DEFENSES

Defendants Novadoz Pharmaceuticals LLC, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (collectively, “MSN” or “Defendants”), by their counsel, hereby answer the complaint filed by Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation (collectively, “Novartis” or “Plaintiffs”) on January 30, 2025 (the “Complaint”) and state as follows:

INTRODUCTION¹

1. Paragraph 1 contains legal conclusions to which no response is

¹ The headings and subheadings in the Complaint do not require a response. Any reproduction in this Answer is solely for convenience and should not be taken as an admission of any fact asserted in any heading or subheading.

required. To the extent that a response is required, MSN admits that Novartis has filed a lawsuit against MSN and denies the remaining allegations contained in paragraph 1 of the Complaint.

2. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint.

3. MSN admits that Entresto is widely regarded as effective in treating heart failure. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 3 of the Complaint.

4. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint.

5. MSN denies that patients and healthcare providers “readily recognize” Entresto’s design as a source identifier, and denies that the “shapes, sizes, and colors of the three-tablet regimen for Entresto” are “distinctive.” MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 5 of the Complaint.

6. MSN admits that MSN has developed a generic equivalent of Novartis’s Entresto drug in conformity with the U.S. Food and Drug Administration’s (“FDA”) Abbreviated New Drug Application (“ANDA”) protocols. MSN denies the remaining allegations contained in paragraph 6 of the Complaint.

7. MSN admits that MSN intends to distribute and sell their generic equivalent of Entresto in the United States under the name NOVADOZ which has been registered with the U.S. Patent and Trademark Office since 2019 and is the U.S. marketing arm for dozens of MSN drugs. MSN denies the remaining allegations contained in paragraph 7 of the Complaint.

8. MSN admits that MSN has developed a generic equivalent of Entresto with plans to distribute and sell the generic equivalent of Entresto in the United States under the brand NOVADOZ. MSN denies the remaining allegations contained in paragraph 8 of the Complaint.

9. MSN denies the allegations contained in paragraph 9 of the Complaint.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 10 of the Complaint.

THE PARTIES

11. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint.

12. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint.

13. MSN admits the allegations contained in paragraph 13 of the Complaint.

14. MSN admits that Defendant Novadoz is a New Jersey limited liability company having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN denies the remaining allegations contained in paragraph 14 of the Complaint.

15. MSN admits the allegations contained in paragraph 15 of the Complaint.

JURISDICTION AND VENUE

16. Paragraph 16 contains legal conclusions to which no response is required. To the extent that a response is required, MSN does not dispute the Court's subject-matter jurisdiction at this time.

17. Paragraph 17 contains legal conclusions to which no response is required. To the extent that a response is required, MSN does not dispute the Court's personal jurisdiction over MSN Labs at this time and otherwise denies the allegations in this paragraph.

18. Paragraph 18 contains legal conclusions to which no response is required. To the extent that a response is required, MSN does not dispute the Court's personal jurisdiction over MSN Pharma at this time.

19. Paragraph 19 contains legal conclusions to which no response is required. To the extent that a response is required, MSN does not dispute the Court's personal jurisdiction over Novadoz Pharma at this time.

20. Paragraph 20 contains legal conclusions to which no response is required. To the extent that a response is required, MSN does not at this time dispute that venue is proper in this judicial district.

FACTUAL BACKGROUND

21. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 21 of the Complaint.

22. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 22 of the Complaint.

23. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 23 of the Complaint.

24. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 24 of the Complaint.

25. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 25 of the Complaint.

26. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26 of the Complaint.

27. To the extent that paragraph 27 of the Complaint contains visual representations of Novartis's Kisqali or Leqvio drugs, MSN states that the packaging for those drugs provides the best evidence of the truth of the packaging's contents. MSN denies knowledge or information sufficient to form a belief as to the truth of

the allegations contained in paragraph 27 of the Complaint.

28. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 28 of the Complaint.

29. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29 of the Complaint.

30. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 30 of the Complaint.

31. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31 of the Complaint.

32. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 32 of the Complaint.

33. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 33 of the Complaint.

34. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 34 of the Complaint.

35. To the extent paragraph 35 purports to characterize the social media posts cited in paragraph 35 of the Complaint, MSN states that the posts speak for themselves and respectfully refers to the posts for their full and complete contents. MSN denies the remaining allegations contained in paragraph 35 of the Complaint.

36. MSN denies knowledge or information sufficient to form a belief as to

the truth of the allegations contained in paragraph 36 of the Complaint.

37. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 37 of the Complaint.

38. MSN denies the allegations contained in paragraph 38 of the Complaint.

39. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 39 of the Complaint.

40. Paragraph 40 contains legal conclusions to which no response is required. To the extent a further response is required, MSN denies knowledge and information sufficient to form a belief as to the allegations contained in paragraph 40 of the Complaint.

41. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 41 of the Complaint.

42. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 42 of the Complaint.

43. MSN denies the allegations contained in paragraph 43 of the Complaint.

44. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 44 of the Complaint.

45. MSN denies knowledge or information sufficient to form a belief as to

the truth of the allegations contained in paragraph 45 of the Complaint.

46. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 46 of the Complaint.

47. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 47 of the Complaint.

48. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 48 of the Complaint.

49. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 49 of the Complaint.

50. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 50 of the Complaint.

51. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 51 of the Complaint.

52. MSN admits the allegations contained in paragraph 52 of the Complaint.

53. MSN admits that the active ingredient in Entresto is a single sacubitril/valsartan complex, and that since its launch in 2015, Entresto is the only tablet that contains such a complex, and that the administered sacubitril/valsartan complex helps patients suffering from chronic heart failure. MSN denies the remaining allegations contained in paragraph 53 of the Complaint.

54. MSN admits the allegations contained in paragraph 54 of the Complaint.

55. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 55 of the Complaint.

56. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 56 of the Complaint.

57. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Complaint.

58. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 58 of the Complaint.

59. The portions of paragraph 59 of the Complaint that purport to define certain terms do not require a response. MSN denies that the combination of size, shape, and color of any Entresto tablet is unique, and denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN admits the remaining allegations contained in the first and third sentences of paragraph 59 of the Complaint.

60. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge or information sufficient to form a belief as to the

truth of the remaining allegations contained in paragraph 60 of the Complaint.

61. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 61 of the Complaint.

62. MSN denies the allegations in paragraph 62 of the Complaint.

63. Paragraph 63 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 63 of the Complaint.

64. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 64 of the Complaint.

65. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 65 of the Complaint.

66. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. To the extent paragraph 66 purports to characterize a purported dosing flash

card, MSN states that the flash card speaks for itself and respectfully refers to the flash card for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 66 of the Complaint.

67. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. To the extent paragraph 67 purports to characterize Entresto's purported Initiation Guide for Providers, MSN states that the Guide speaks for itself and respectfully refers to the Guide for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 67 of the Complaint.

68. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. To the extent paragraph 68 purports to characterize from the contents of a Novartis website, MSN states that the website speaks for itself and respectfully refers to the website for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 68 of the Complaint.

69. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto

tablets. To the extent paragraph 69 purports to characterize a purported Dosing and Titration Guide, MSN states that the Guide speaks for itself and respectfully refers to the Guide for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 69 of the Complaint.

70. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 70 of the Complaint.

71. MSN denies the allegations contained in paragraph 71 of the Complaint.

72. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. To the extent paragraph 72 purports to characterize a purported in-office brochure, MSN states that the brochure speaks for itself and respectfully refers to the brochure for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 72 of the Complaint.

73. To the extent paragraph 73 purports to characterize a guide offered with a purported Heading Home Digital Kit, MSN states that the guide speaks for itself

and respectfully refers to the guide for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 73 of the Complaint.

74. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 74 of the Complaint.

75. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. To the extent paragraph 75 purports to characterize the Novartis/Entresto website, MSN states that the website speaks for itself and respectfully refers to the website for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 75 of the Complaint.

76. To the extent paragraph 76 purports to characterize the news articles cited in paragraph 76 and footnotes 29–37 of the Complaint, MSN states that the articles speak for themselves and respectfully refers to the articles for their full and complete contents. MSN denies the remaining allegations contained in paragraph 76 of the Complaint.

77. MSN denies that the look and feel of the Entresto tablets are distinctive. MSN denies knowledge and information sufficient to form a belief as to the remaining allegations contained in paragraph 77 of the Complaint.

78. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 78 of the Complaint.

79. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 79 of the Complaint.

80. MSN denies the allegations contained in paragraph 80 of the Complaint.

81. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 81 of the Complaint.

82. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 82 of the Complaint.

83. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 83 of the Complaint.

84. To the extent paragraph 84 purports to characterize the photos cited in paragraph 86 of the Complaint, MSN states that the photos speak for themselves and respectfully refers to the websites cited containing those photos for their full and complete contents. MSN denies the remaining allegations contained in paragraph 84 of the Complaint.

85. MSN denies the allegations contained in paragraph 85 of the Complaint.

86. Paragraph 86 contains legal conclusions to which no response is

required. To the extent that a response is required, MSN denies the allegations contained in paragraph 86 of the Complaint.

87. Paragraph 87 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 87 of the Complaint.

88. MSN denies that Novadoz is an affiliate of MSN Labs and, as such, MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 88 of the Complaint. Further, paragraph 88 contains legal conclusions to which no response is required.

89. MSN admits that MSN has received FDA approval to distribute and sell a generic equivalent of Entresto in the United States. MSN also admits that MSN and Novartis are currently involved in a separate patent litigation pending before District of Delaware Court and that there was an injunction in place pending appeal before the Federal Circuit. MSN avers that the Federal Circuit injunction in place as of the date of the filing of the Complaint has since lifted and that litigation is proceeding in the District of Delaware matter *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, No. 24-CV-2234 (D. Del.). MSN denies the remaining allegations contained in paragraph 89 of the Complaint.

90. MSN denies the allegations contained in paragraph 90 of the Complaint

91. To the extent paragraph 91 purports to characterize the FDA-approved

label for MSN's generic equivalent of Entresto cited in paragraph 91 and footnote 50 of the Complaint, MSN states that the label speaks for itself and respectfully refers to the label for its full and complete contents. MSN denies knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 91 of the Complaint.

92. To the extent paragraph 92 purports to characterize the FDA-approved label for MSN's generic equivalent of Entresto cited in paragraph 92 and footnote 51 of the Complaint, MSN states that the label speaks for itself and respectfully refers to the label for its full and complete contents. MSN denies the remaining allegations contained in paragraph 92 of the Complaint.

93. MSN denies the allegations contained in paragraph 93 of the Complaint.

94. To the extent paragraph 94 purports to characterize the FDA-approved labels for MSN's generic equivalent of Entresto and Novartis's Entresto, cited in paragraph 94 and footnote 53 of the Complaint, MSN states that the labels speak for themselves and respectfully refers to the labels for their full and complete contents. MSN denies the remaining allegations contained in paragraph 94 of the Complaint.

95. MSN admits that MSN Labs will manufacture MSN's generic tablets and admits that Novadoz Pharma sells generic pharmaceuticals in the United States under the NOVADOZ brand name. MSN denies the remaining allegations contained

in paragraph 95 of the Complaint.

96. MSN admits that Novadoz has used the NOVADOZ trademark to market and sell MSN's generic pharmaceuticals in the United States since August 2018. MSN also admits that Novartis contacted MSN about its application to register NOVADOZ in September 2019 and failed to take any subsequent action until the filing of this lawsuit in January 2025. MSN denies knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 96 of the Complaint.

97. MSN denies the allegations contained in Paragraph 97 of the Complaint.

98. To the extent paragraph 98 purports to characterize the contents of the official FDA Drug Database cited in paragraph 98 and footnote 55 of the Complaint, MSN states that the Database speaks for itself and respectfully refers to the Database for its full and complete contents. In addition, to the extent paragraph 98 purports to characterize the FDA-approved label for MSN's generic equivalent of Entresto cited in paragraph 98 of the Complaint, MSN states that the label speaks for itself and respectfully refers to the label for its full and complete contents. MSN denies knowledge and information sufficient to form a belief as to the truth of the assertion that Novartis "discovered" updates to the FDA's Drug Database or a new package insert on January 20, 2025. MSN denies the remaining allegations in paragraph 98

of the Complaint.

99. To the extent that Novartis claims that the photo shown in paragraph 99 represents a version of the label for MSN's generic equivalent of Entresto, MSN states that the label speaks for itself and respectfully refers to the document from which this label was pulled for its full and complete contents. MSN denies knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 99 of the Complaint.

100. Paragraph 100 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 100 of the Complaint.

101. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 101 of the Complaint.

102. MSN admits that Novadoz maintains a website available at <https://novadozpharma.com/view-products/> and that this website prominently features the NOVADOZ mark. To the extent paragraph 102 purports to characterize the Novadoz webpage cited in paragraph 102 of the Complaint, MSN states that the webpage speaks for itself and respectfully refers to the webpage for its full and complete contents.

103. MSN denies the allegations contained in paragraph 103 of the Complaint.

104. Paragraph 104 contains legal conclusions regarding likelihood of confusion as to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 104 of the Complaint.

105. MSN denies knowledge and information sufficient to form a belief as to the truth of the allegations regarding Sandoz's sale of Novartis products and use of the SANDOZ and/or NOVARTIS brand names. MSN denies the remaining allegations contained in paragraph 105 of the Complaint.

106. Paragraph 106 contains legal conclusions regarding likelihood of confusion as to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 106 of the Complaint.

107. MSN denies the allegations contained in paragraph 107 of the Complaint.

108. MSN denies the allegations contained in paragraph 108 of the Complaint.

109. MSN denies the allegations contained in paragraph 109 of the Complaint.

110. MSN denies the allegations contained in paragraph 110 of the Complaint.

111. Paragraph 111 contains legal conclusions to which no response is required. To the extent that a response is required, MSN admits that in certain states

pharmacists are permitted to substitute generic drugs with an “AB” rating for their branded equivalents.

112. MSN admits that MSN’s generic equivalent of Entresto received an “AB” rating from the FDA. The remainder of paragraph 112 contains legal conclusions to which no response is required. To the extent that a response is required, MSN denies the allegations contained in paragraph 112 of the Complaint.

113. Paragraph 113 contains legal conclusions to which no response is required. To the extent that a response is required, MSN admits that patients have the option to instruct their physicians that they would prefer to receive a branded drug rather than a generic alternative.

114. MSN denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets. MSN denies knowledge and information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 114 of the Complaint.

115. MSN denies the allegations contained in paragraph 115 of the Complaint.

116. MSN denies the allegations contained in paragraph 116 of the Complaint.

117. MSN denies the allegations contained in paragraph 117 of the Complaint.

118. MSN denies the allegations contained in paragraph 118 of the Complaint.

119. MSN denies the allegations contained in paragraph 119 of the Complaint.

120. MSN denies the allegations contained in paragraph 120 of the Complaint.

121. MSN denies the allegations contained in paragraph 121 of the Complaint.

122. MSN denies the allegations contained in paragraph 122 of the Complaint.

123. MSN admits the allegations contained in paragraph 123 of the Complaint.

124. MSN denies the allegations contained in paragraph 124 of the Complaint.

125. MSN denies the allegations contained in paragraph 125 of the Complaint.

126. MSN denies the allegations contained in paragraph 126 of the Complaint.

127. MSN denies the allegations contained in paragraph 127 of the Complaint.

COUNT ONE

**Trademark Infringement
Section 32 of the Lanham Act, 15 U.S.C. § 1114**

128. MSN repeats and realleges each and every response to paragraphs 1 to 127 of the Complaint as if fully set forth herein.

129. Paragraph 129 contains legal conclusions to which no response is required. To the extent a further response is required, MSN denies knowledge and information sufficient to form a belief as to the allegations contained in paragraph 129 of the Complaint.

130. MSN denies the allegations contained in paragraph 130 of the Complaint.

131. MSN denies the allegations contained in paragraph 131 of the Complaint.

132. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 132 of the Complaint.

133. MSN denies the allegations contained in paragraph 133 of the Complaint.

134. MSN denies the allegations contained in paragraph 134 of the Complaint.

135. MSN denies the allegations contained in paragraph 135 of the Complaint.

136. MSN denies the allegations contained in paragraph 136 of the Complaint.

137. MSN denies the allegations contained in paragraph 137 of the Complaint.

138. MSN denies the allegations contained in paragraph 138 of the Complaint.

COUNT TWO

False Designation of Origin Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)

139. MSN repeats and realleges each and every response to paragraphs 1 to 138 of the Complaint as if fully set forth herein.

140. MSN denies the allegations contained in paragraph 140 of the Complaint.

141. MSN denies the allegations contained in paragraph 141 of the Complaint.

142. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 142 of the Complaint.

143. MSN denies the allegations contained in paragraph 143 of the Complaint.

144. MSN denies the allegations contained in paragraph 144 of the Complaint.

145. MSN denies the allegations contained in paragraph 145 of the Complaint.

146. MSN denies the allegations contained in paragraph 146 of the Complaint.

147. MSN denies the allegations contained in paragraph 147 of the Complaint.

148. MSN denies the allegations contained in paragraph 148 of the Complaint.

149. MSN denies the allegations contained in paragraph 149 of the Complaint.

COUNT THREE

Trade Dress Infringement Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)

150. MSN repeats and realleges each and every response to paragraphs 1 to 149 of the Complaint as if fully set forth herein.

151. MSN denies the allegations contained in paragraph 151 of the Complaint.

152. Paragraph 152 contains legal conclusions to which no response is required. To the extent that a further response is required, MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 152 of the Complaint, except denies that Novartis possesses trade dress

rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets.

153. MSN denies the allegations contained in paragraph 153 of the Complaint.

154. MSN denies the allegations contained in paragraph 154 of the Complaint.

155. MSN denies the allegations contained in paragraph 155 of the Complaint.

156. MSN denies the allegations contained in paragraph 156 of the Complaint.

157. MSN denies the allegations contained in paragraph 157 of the Complaint.

158. MSN denies the allegations contained in paragraph 158 of the Complaint.

159. MSN denies the allegations contained in paragraph 159 of the Complaint.

160. MSN denies the allegations contained in paragraph 160 of the Complaint.

COUNT FOUR

**Trademark Infringement
N.J. S.A. § 56:4-1 et seq.**

161. MSN repeats and realleges each and every response to paragraphs 1 to 160 of the Complaint as if fully set forth herein.

162. Paragraph 162 contains legal conclusions to which no response is required. To the extent a further response is required, MSN denies knowledge and information sufficient to form a belief as to the allegations contained in paragraph 162 of the Complaint.

163. MSN denies the allegations contained in paragraph 163 of the Complaint.

164. MSN denies the allegations contained in paragraph 164 of the Complaint.

165. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 165 of the Complaint.

166. MSN denies the allegations contained in paragraph 166 of the Complaint.

167. MSN denies the allegations contained in paragraph 167 of the Complaint.

168. MSN denies the allegations contained in paragraph 168 of the Complaint.

169. MSN denies the allegations contained in paragraph 169 of the Complaint.

170. MSN denies the allegations contained in paragraph 170 of the Complaint.

171. MSN denies the allegations contained in paragraph 171 of the Complaint.

COUNT FIVE

**Trade Dress Infringement
N.J. S.A. § 56:4-1 et seq.**

172. MSN repeats and realleges each and every response to paragraphs 1 to 171 of the Complaint as if fully set forth herein.

173. MSN denies the allegations contained in paragraph 173 of the Complaint.

174. Paragraph 174 contains legal conclusions to which no response is required. To the extent that a further response is required, MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 174 of the Complaint, except denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets.

175. MSN denies the allegations contained in paragraph 175 of the Complaint.

176. MSN denies the allegations contained in paragraph 176 of the Complaint.

177. MSN denies the allegations contained in paragraph 177 of the Complaint.

178. MSN denies the allegations contained in paragraph 178 of the Complaint.

179. MSN denies the allegations contained in paragraph 179 of the Complaint.

180. MSN denies the allegations contained in paragraph 180 of the Complaint.

181. MSN denies the allegations contained in paragraph 181 of the Complaint.

182. MSN denies the allegations contained in paragraph 182 of the Complaint.

183. MSN denies the allegations contained in paragraph 183 of the Complaint.

COUNT SIX

Common Law Unfair Competition and Trademark Infringement

184. MSN repeats and realleges each and every response to paragraphs 1 to 183 of the Complaint as if fully set forth herein.

185. Paragraph 185 contains legal conclusions to which no response is required. To the extent a further response is required, MSN denies knowledge or

information sufficient to form a belief as to the truth of the allegations contained in paragraph 185 of the Complaint.

186. MSN denies the allegations contained in paragraph 186 of the Complaint.

187. MSN denies the allegations contained in paragraph 187 of the Complaint.

188. MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 188 of the Complaint.

189. MSN denies the allegations contained in paragraph 189 of the Complaint.

190. MSN denies the allegations contained in paragraph 190 of the Complaint.

191. MSN denies the allegations contained in paragraph 191 of the Complaint.

192. Defendants deny the allegations contained in paragraph 192 of the Complaint.

193. MSN denies the allegations contained in paragraph 193 of the Complaint.

194. MSN denies the allegations contained in paragraph 194 of the Complaint.

COUNT SEVEN

Common Law Unfair Competition and Trademark Infringement

195. MSN repeats and realleges each and every response to paragraphs 1 to 194 of the Complaint as if fully set forth herein.

196. MSN denies the allegations contained in paragraph 196 of the Complaint.

197. Paragraph 197 contains legal conclusions to which no response is required. To the extent that a further response is required, MSN denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 197 of the Complaint, except denies that Novartis possesses trade dress rights in the size, shape, color, or appearance of the individual Entresto tablets or any combination of Entresto tablets.

198. MSN denies the allegations contained in paragraph 198 of the Complaint.

199. MSN denies the allegations contained in paragraph 199 of the Complaint.

200. MSN denies the allegations contained in paragraph 200 of the Complaint.

201. MSN denies the allegations contained in paragraph 201 of the Complaint.

202. MSN denies the allegations contained in paragraph 202 of the Complaint.

203. MSN denies the allegations contained in paragraph 203 of the Complaint.

204. MSN denies the allegations contained in paragraph 204 of the Complaint.

205. MSN denies the allegations contained in paragraph 205 of the Complaint.

COUNT EIGHT

Declaratory Judgment

206. MSN repeats and realleges each and every response to paragraphs 1 to 205 of the Complaint as if fully set forth herein.

207. MSN denies the allegations contained in paragraph 207 of the Complaint.

208. MSN denies the allegations contained in paragraph 208 of the Complaint.

209. MSN denies the allegations contained in paragraph 209 of the Complaint.

210. MSN denies the allegations contained in paragraph 210 of the Complaint.

211. MSN denies the allegations contained in paragraph 211 of the Complaint.

212. MSN denies the allegations contained in paragraph 212 of the Complaint.

AFFIRMATIVE DEFENSES

Pursuant to Rule 8(c) of the Federal Rules of Civil Procedure, MSN further pleads the following separate and additional defenses. MSN's assertion of the following defenses does not shift the burden of proof, and MSN does not in any way agree or concede that they have the burden of proof or persuasion as to any of these issues. MSN reserves the right to assert such additional affirmative defenses as discovery indicates are proper.

FIRST DEFENSE

Novartis's claims are barred, in whole or in part, because they fail to state a claim upon which relief can be granted.

SECOND DEFENSE

Novartis's claims are barred, in whole or in part, because consumers are not likely to be confused with regard to the source of MSN's generic equivalent of Entresto.

THIRD DEFENSE

Novartis's claims are barred, in whole or in part, because Novartis's claimed trade dress is invalid because it is generic and/or lacks secondary meaning.

FOURTH DEFENSE

Novartis's claims are barred, in whole or in part, because Novartis's claimed trade dress is invalid because its claimed trade dress comprises matter that as a whole is functional.

FIFTH DEFENSE

Novartis's claims are barred, in whole or in part, because MSN's use constitutes fair use.

SIXTH DEFENSE

Novartis's claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or acquiescence.

SEVENTH DEFENSE

Novartis's claims are barred, in whole or in part, by the doctrine of equitable estoppel.

EIGHTH DEFENSE

Novartis's claims are barred, in whole or in part, by the doctrine of unclean hands.

NINTH DEFENSE

Novartis's claims are barred, in whole or in part, because MSN acted in good faith and employed lawful, proper, and justified means to accomplish legitimate business objectives.

TENTH DEFENSE

Novartis's claims are barred, in whole or in part, because MSN did not engage in any deceptive or unfair acts or practices.

ELEVENTH DEFENSE

Novartis's claims are barred, in whole or in part, because MSN did not act with the requisite degree of knowledge, intent, or fault.

TWELFTH DEFENSE

Novartis's claims are barred, in whole or in part, because Novartis suffered and will suffer no injury or damages.

THIRTEENTH DEFENSE

Novartis's claims are barred, in whole or in part, because Novartis's damages, if any, are vague, uncertain, imaginary, or speculative.

FOURTEENTH DEFENSE

Novartis's claims are barred, in whole or in part, because Novartis failed to mitigate its damages.

FIFTEENTH DEFENSE

Novartis's claims for injunctive relief are barred, in whole or in part, because Novartis suffered no irreparable harm.

SIXTEENTH DEFENSE

Novartis's claims for injunctive relief are barred, in whole or in part, because Novartis has an adequate remedy at law.

SEVENTEENTH DEFENSE

Novartis's claims are barred, in whole or in part, because it lacks standing to assert a claim premised in whole or in part on a trademark it does not own.

EIGHTEENTH DEFENSE

Novartis's claims are barred, in whole or in part, because any rights it ever had in its so-called Entresto trade dress have been abandoned through a course of conduct including acquiescence in widespread third-party use that caused the trade dress to lose any distinctiveness that may have ever existed.

RESERVATION OF RIGHTS

MSN reserves the right to amend and/or supplement this Answer, Defenses, and Affirmative Defenses including, without limitation, to assert additional defenses.

Dated: May 6, 2025

Respectfully submitted,

/s/ Rebekah Conroy

Rebekah Conroy

STONE CONROY LLC

25A Hanover Road, Suite 301

Florham Park, New Jersey 07932

(973) 400-4181

rconroy@stoneconroy.com

Ron Daignault (admitted *pro hac vice*)

Richard Juang (admitted *pro hac vice*)

DAIGNAULT IYER LLP

8229 Boone Boulevard, Suite 450

Vienna, VA 22182

(917) 838-9795

rdaignault@daignaultiyer.com

rjuang@daignaultiyer.com

Gianni P. Servodidio (admitted *pro hac vice*)

Jacquellena T. Carrero (admitted *pro hac vice*)

JENNER & BLOCK LLP

1155 Avenue of the Americas

New York, NY 10036

Tel: (212) 891-1600

Fax: (212) 891-1699

gservodidio@jenner.com

jcarrero@jenner.com

Attorneys for Defendants

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants, by their undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

/s/ Rebekah Conroy
Rebekah Conroy

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of May, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

/s/ Rebekah Conroy
Rebekah Conroy